

Title:

Semaglutide for Smoking Cessation in Patients with Diabetes: A Pilot Randomized Controlled Trial (GLP1-SC)

Investigator:

- Dr. Hassan Mir, University of Ottawa Heart Institute

Description of the Study:

Tobacco smoking remains a major cause of preventable morbidity and mortality, particularly among individuals with type 2 diabetes mellitus (T2DM), who face substantially increased cardiovascular risk. Smoking cessation is characterized by high relapse rates, driven in part by nicotine withdrawal and post-cessation weight gain. Glucagon-like peptide-1 receptor agonists (GLP-1 RAs), such as semaglutide, improve glycaemic control, promote weight loss, and may modulate neurobiological pathways involved in nicotine dependence. However, the feasibility of integrating GLP-1 RA therapy into smoking cessation care for individuals with T2DM has not been established.

Funding Source:

Ottawa Heart Institute Research Corporation (OHIRC)

Project Start Date: December 5, 2025

Project End Date: August 5, 2027

Inclusion Criteria:

- Adults (18 years or older) with type 2 diabetes
- Currently residing in Ontario
- Smoke at least five cigarettes per day and willing to reduce or quit smoking within the next 6 months
- Stable HbA1c $\geq 7.0\%$ - 10% with no more than a 1% change over the last 3 to 6 months.
- Have not used GLP-1 receptor agonists in the past six months.
- Able to provide informed consent

Ethics Approval:

Ottawa Health Science Network Research Ethics Board

Participation:

The study specifically involves adults with type 2 diabetes who smoke. Diabetes is an important part of the study population because the study is looking at whether adding semaglutide to standard smoking-cessation treatment can help people with diabetes quit smoking, while also monitoring diabetes-related outcomes.

Participants are adults with type 2 diabetes who smoke at least 5 cigarettes per day and are interested in reducing or quitting smoking. Potential participants are screened for eligibility, and those who meet the criteria and provide informed consent are enrolled in the study, participants are randomized 1:1 into one of two groups:

- Semaglutide + combination NRT(Nicotine patch + short-acting NRT (gum or lozenge))
- Combination NRT alone

The study collects information on participants' smoking habits and cessation, diabetes control (HbA1c), medications, weight, height, waist circumference, treatment adherence, and safety/adverse events. Participants also complete questionnaires assessing nicotine dependence/withdrawal, mental health, and quality of life.

Participant Safety and Privacy:

Adverse Events

- Adverse events will be monitored through regular clinical assessments and self-reports. Success will be indicated by the absence of severe adverse events and an acceptable tolerability profile (fewer than 15% of participants discontinuing due to side effects).
- The known side effects related to the use of semaglutide include headache, dizziness, tiredness and GI issues such as heartburn, nausea, vomiting, diarrhea, constipation.
- The known side effects of the NRT patch include skin irritation (itchiness/redness) at the patch site, headaches, dizziness and sleep disturbances. The short-acting NRT (gum and lozenge) have side effects such as mouth irritation, nausea, sore throat and headaches.
- Side effects included above are typically managed by reducing the dose or stopping the medication all together. Those side effects noted above will not be reported as adverse events unless the event is significant in nature and the participant requires immediate medical attention (e.g. visit to the Emergency Department or prolonged hospitalization).
- A study-specific standard operating procedure has been put in place to outline the collection, classification and reporting of adverse events as noted above. This SOP is referenced in the Trial Master File.
- One of the study physicians will review all blood test results. In the case of an abnormal result, the study team will notify the participant and if required, a study

doctor will assess the participant either in person at UOHI or virtually and advise on next steps.

Data Safety Monitoring Board

- A Data Safety Monitoring Board (DSMB) has been established. They will provide an independent review of all adverse events and provide recommendations on study-related safety data. A full outline of the DSMB activities are found within the DSMB charter.

Study Monitoring

- The study will be internally monitored by the Clinical Research and Compliance office at UOHI. A study-specific monitoring plan will be followed for the duration of the study. If required, the Compliance Office can request additional monitoring visits based on the findings from previous visits. The specific monitoring plan can be found within the study file and is referenced in the Trial Master File.

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